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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/509,734	06/14/00	ITESCU	31856-PCT

EXAMINER

021003
BAKER & BOTTS
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NEW YORK NY 10112

HM12/0601

ART UNIT	PAPER NUMBER
1644	5

DATE MAILED: 06/01/01

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ONE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1 – 19 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☑ Claim(s) 1 – 19 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I claim(s) 1-7 and 19 drawn to assessing risk of transplantation rejection via detection of activated T-cells and IgG anti-HLA Class II antibodies.

Group II, claim(s) 8-9 and 13-16, drawn to kits containing solid phase HLA antigens and a reagent for detecting IgG.

Group III, claim(s) 10-11, drawn to kits containing complement and a denaturing agent.

Group IV, claim(s) 12, drawn to kits containing cells and labeled anti-IgG.

Group V, claim(s) 17-18, drawn to methods of detecting and comparing anti-HLA antibody reactivity against B-cells versus T-cells.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The testing methods of Groups I and V involve different steps (e.g. only Group II requires determining the ratio of anti-HLA reactivity to B-cells versus T-cells), involve use of different reagents (e.g. only Group II requires use of DTT), and can be conducted upon patients other than transplant patients (e.g. multiple transfused patients or multiparous women). These methods thus do not have the same special technical feature to provide for unity of invention.

The components of the kits of Groups II-IV bear no clear relationship to the methods of Groups I and V and thus do not provide for a single inventive concept. For example, the kits of Groups II and IV require provision of a means for detecting IgG antibody or a labeled IgG antibody, but use of such a reagent is not recited in the method of Groups I or V. The kit of Group III requires provision of complement and a denaturing agent; the method of Group I does not require use of a denaturing agent, and the method of Group V does not require use of complement. Further, even if it were considered that there is a nexus between the kits of Groups II-IV and the methods of Groups I and V, it is to be noted that if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application

and the first recited invention of each of the other categories related thereto will be considered as the main invention of the claims (PCT Article 17(3)(a)). Therefore, at most, applicant could only consider the first recited method and first recited kit as constituting the main invention.

Further, the kits of Groups II-IV would have uses in conducting methods other than those of Groups V and V. For example, they could be used in HLA typing to determine autoimmune disease associations. The kit of Group II could be used to conduct a complement fixation test or a Jerne plaque assay. In any case, the components of the kits of Groups II-IV are old and known for HLA typing, complement fixation assays, and in Jerne plaque assays. The kits therefore do not constitute a contribution by applicant over the prior art and thus cannot be considered as involving an inventive concept under PCT Rule 13.1

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Friday (8:15-4:45).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications.

The fax number for responses to restrictions is (703) 305-3704. Use attached form.

David A Saunders

das
May 30, 2001

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY FOR RESPONSES TO RESTRICTIONS.

COMMENTS:_____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.